RESETTABLE SAFETY SHIELD FOR MEDICAL NEEDLES

BACKGROUND

1. Technical Field

The present disclosure generally relates to safety shields for medical needles, and more particularly, to safety shields that protect a needle point of a medical needle.

2. Description of the Related Art

Problems associated with inadvertent needle sticks are well known in the art of blood sampling, percutaneous medication injection and other medical procedures involving use of medical needles. Significant attention has been focused on needle stick problems due to the contemporary sensitivity of exposure to AIDS, Hepatitis and other serious blood-borne pathogen exposures.

Procedures for removing a needle from a patient commonly require a technician to use one hand to place pressure at the wound site where the needle is being withdrawn, while removing the needle device with the other hand. It is also common practice for an attending technician to give higher priority to care for the patient than is given to disposal of a needle. In the case of typical needle devices without safety shields, such priority either requires the convenience of an available sharps container within reach or another means for safe disposal without leaving the patient's side. Providing adequate care while following safety procedures is often compounded by the patient's physical condition and mental state, such as in burn units and psychiatric wards. Under such conditions, it is difficult to properly dispose of a used needle while caring for a patient.

The widespread knowledge and history associated with needle care and disposal problems have resulted in numerous devices for preventing accidental needle sticks. Problems of current safety devices include difficulty of use and high cost due to their complexity and number of parts.

Other known devices employ sheaths that are spring activated, telescoping, pivoting, etc. These devices, however, may disadvantageously misfire or be cumbersome to activate. Further drawbacks of current devices include high manufacturing cost due to complexity and the number of parts. Thus, these type prior art devices may not adequately and reliably shield medical needle apparatus to prevent hazardous exposure.

Consequently, there remains a need to provide a more satisfactory solution for needle safety devices by overcoming the disadvantages and drawbacks of the prior art. Therefore, it would be desirable to provide a more adequate and reliable medical needle shield apparatus that employs a safety shield slidably movable along a medical needle to prevent hazardous exposure to a needle tip. It would be advantageous to provide such a safety shield that is capable of being reset to safely allow re-use of certain needle apparatus. Such a needle shield apparatus should be easily and reliably movable to shield a needle tip of a needle cannula.

SUMMARY

Accordingly, the present disclosure addresses a need for a medical needle shield apparatus which effectively and inexpensively protects a tip of a medical needle after use. The present disclosure resolves related disadvantages and drawbacks experienced in the art. More specifically, the apparatus and method of this invention constitute an important advance in the art of safety needle devices.

In one particular embodiment, a medical needle shield apparatus is provided in accordance with the principles of the present disclosure. The medical needle shield apparatus includes a shield that is extensible from a retracted position to an extended position to enclose a distal end of a needle. A binding member is disposed within the shield and defines binding surfaces that form an aperture configured for slidable receipt of the needle between the retracted position and the extended position. The binding member includes at least one drag inducing member that is configured for slidable engagement with the needle between the retracted position and the extended position such that the at least one drag inducing member engages the needle to create a drag force with the needle. The drag force facilitates rotation, as will be discussed, of the binding member relative to a longitudinal axis of the needle such that the binding surfaces engage the needle to prevent slidable movement of the needle in the extended position of the shield. The binding member further includes a retainer extending therefrom such that the retainer is engageable with the needle to prevent rotation of the binding member.

In another particular embodiment, a medical needle shield apparatus includes a needle hub having an outer needle cannula extending therefrom to a distal end. An inner needle is disposed for slidable movement with the outer needle cannula. At least one shield is extensible from a retracted position to an extended position to

enclose a distal end of the inner needle. The shield includes a binding member disposed within the shield and defines binding surfaces that form an aperture configured for slidable receipt of the inner needle between the retracted position and the extended position.

The binding member includes at least one drag inducing member such that the member engages the inner needle during slidable receipt of the inner needle to create a drag force with the inner needle. The drag force facilitates rotation of the binding member relative to a longitudinal axis of the inner needle such that the binding surfaces engage the inner needle to prevent slidable movement of the inner needle in the extended position of the shield. The binding member further includes a needle communicating surface extending therefrom such that the needle communicating surface is engageable with the inner needle to prevent rotation of the binding member. A retainer extends transversely from the binding member for releasable engagement with the needle hub.

The binding member may be rotatable, relative to a longitudinal axis of the inner needle, between a non-binding orientation whereby the inner needle is slidable relative to the binding member and a binding orientation whereby the binding surfaces engage the inner needle to prevent slidable movement of the inner needle in the extended position of the at least one shield. The binding member may include one or more outwardly arcuate arms that extend to the needle-communicating surface.

The inner needle can be attached to a handle for manipulation thereof. The needle hub may define a hub slot configured for receipt of the retainer. The needle hub may be releasably mountable with a housing of the at least one shield. The medical needle shield apparatus may further include a plurality of shields.

The at least one drag inducing member may define a cavity that is substantially aligned with the aperture. The cavity is configured for slidable receipt of the needle to create the drag force with the needle. The binding member may include a substantially planar aperture plate that includes the binding surfaces that form the aperture. The at least one drag inducing member may include a pair of arms extending from the aperture plate. The arms can have curled end portions spaced apart from the aperture plate. The arms can include deflectable members.

The shield can include a housing that defines at least one blocking member extending from an interior surface thereof. The at least one blocking member can be

engageable with the binding member for urging the binding member to a binding orientation. The aperture plate is axially movable for engagement with the at least one blocking member that causes rotation of the binding member to a binding orientation.

A binding member may include a reset surface which extends transversely from the binding member. The needle hub may also include a reset surface aligned to contact with the binding member reset surface of an activated binding member when the shield housing is brought to mate concentrically with the needle hub. The reset surface deflects the binding member reset surface along with the needle engagement surface to a position above the inner needle surface and urges the binding member from the binding orientation to the sliding orientation. Concurrently, due to contact between the reset surface and binding member reset surface, the hub retainer is urged into a position that reengages the needle hub and retains the needle hub to the needle shield. In an illustrative embodiment, the reset surface is the distal facing surface of the hub retainer.

The medical needle shield apparatus may further be supported for relative rotational movement by at least one bearing.

In an alternate embodiment, the medical needle shield apparatus includes a shield being extensible from a retracted position to an extended position to enclose a distal end of the outer needle cannula. The shield defines a probe guide at a distal end thereof that is configured for receipt of a probe. The probe is configured for slidable movement with the outer needle cannula.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features and advantages of the present invention will be more fully understood from the following detailed description of the exemplary embodiments, taken in conjunction with the accompanying drawings in which:

FIGURE 1 is a perspective view of one particular embodiment of a medical needle shield apparatus in accordance with the principles of the present disclosure;

FIGURE 2 is a perspective view of the embodiment shown in FIGURE 1 in a shielded configuration;

FIGURE 3 is a cutaway perspective view of a shield of the medical needle shield apparatus shown in FIGURE 1 in a non-binding orientation;

FIGURE 4 illustrates the cutaway perspective view of the medical needle shield apparatus shown in FIGURE 2 in a binding orientation;

FIGURE 5 is a perspective view of the bearing of a needle safety apparatus as shown in FIGURE 1;

FIGURE 6 is a cutaway perspective of the stylet shield of a needle safety apparatus as shown in FIGURE 1;

FIGURE 7 is an enlarged perspective view of a binding member of the medical needle shield apparatus shown in FIGURE 1;

FIGURE 8 is a perspective view of the needle shield apparatus as shown in FIGURE 1 having a protective needle sheath installed thereon;

FIGURE 9 is an alternate enlarged perspective view of the binding member shown in FIGURE 7;

FIGURES 10 – 11 are cutaway perspective views of the medical needle safety apparatus showing engagement between reset surface and binding member reset surface according to the present disclosure;

FIGURE 12 is a cutaway perspective view of an embodiment of the medical needle safety apparatus according to the present disclosure adapted for use with a luer lock needle hub;

FIGURE 13 is a cutaway perspective view the medical needle safety apparatus as shown in FIG 12 in a shielded configuration;

FIGURE 14 is an enlarged perspective view of the medical needle safety apparatus as shown in FIGURE 12 showing engagement between reset surface and binding member reset surface according to the present disclosure;

FIGURE 15 is an enlarged perspective view of the medical needle safety apparatus as shown in FIGURE 12 in a reset configuration;

FIGURE 16 is a perspective view of an embodiment of a medical needle shield apparatus adapted for use with a bone biopsy needle in accordance with the principles of the present disclosure;

FIGURE 17 is an enlarged cross-sectional view of the depth stop assembly shown in FIGURE 16;

FIGURE 18 is an enlarged cross-sectional view of the handle assembly shown in FIGURE 16;

FIGURE 19 is a perspective view of the medical needle shield apparatus shown in FIGURE 16 with the depth stop assembly partially advanced along the threaded sleeve;

FIGURE 20 is a perspective view of the medical needle shield apparatus shown in FIGURE 16 with the stylet partially extended from the needle hub;

FIGURE 21 is a cross-sectional view of the medical needle shield apparatus as shown in FIGURE 20;

FIGURE 22 is a perspective view of the medical needle shield apparatus shown in FIGURE 16 with the stylet shield fully extended from the needle hub;

FIGURE 23A is an enlarged cross-sectional view of the medical needle shield apparatus as shown in FIGURE 22;

FIGURE 23B is an enlarged cross-sectional view of an alternate embodiment of the medical needle shield apparatus shown in FIGURE 22;

FIGURE 24 is a perspective view of the medical needle shield apparatus shown in FIGURE 16 with the stylet removed and a syringe inserted in the needle hub for aspiration purposes;

FIGURE 25 is a perspective view of the medical needle shield apparatus shown in FIGURE 16 with the depth stop assembly removed;

FIGURE 26 is a perspective view of the medical needle shield apparatus shown in FIGURE 16 in the shielded configuration;

FIGURE 27 is an enlarged cross-sectional view of the medical needle shield apparatus shown in FIGURE 26;

FIGURE 28 is a perspective view of an embodiment of a medical needle shield apparatus adapted for use with a PICC introducer in accordance with the principles of the present disclosure;

FIGURE 29 is an alternative perspective view of an embodiment of a medical needle shield apparatus illustrated in FIGURE 28;

FIGURE 30 is an enlarged cutaway perspective view of the embodiment shown in FIG 28 in a retracted position;

FIGURE 31 is a perspective view of the embodiment shown in FIGURE 28 in a shielded configuration;

FIGURE 32 is a cutaway perspective view of the embodiment shown in FIGURE 28 in a shielded configuration;

FIGURE 33 is a cutaway perspective view of the embodiment shown in FIGURE 28 in a reset configuration in accordance with the present disclosure;

FIGURE 34 is a perspective view of an embodiment of a medical needle shield apparatus adapted for use with an implanted port access in accordance with the principles of the present disclosure;

FIGURE 35 is a perspective view of the embodiment shown in FIGURE 34 in an unshielded configuration;

FIGURE 36 is a cutaway perspective view of the embodiment shown in FIGURE 34 in a shielded configuration;

FIGURE 37 is a cutaway perspective view of the embodiment shown in FIGURE 34 in an unshielded configuration;

FIGURE 38 is a perspective view of an embodiment of a medical needle shield apparatus adapted for use with a drug vial access in accordance with the principles of the present disclosure;

FIGURE 39 is a perspective view of the embodiment shown in FIGURE 38 in an unshielded configuration;

FIGURE 40 is cutaway perspective view of the embodiment shown in FIGURE 39 in a shielded configuration;

FIGURE 41 is a cutaway perspective view of the embodiment shown in FIGURE 39 in a reset configuration according to the principles of the present disclosure;

FIGURE 42 is a perspective view of a bearing incorporating reset features of a particular embodiment of the medical shield apparatus;

FIGURE 43 is a perspective view of a binding member embodiment incorporating a reset element;

FIGURE 44 is a perspective view of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 45 is an enlarged cutaway view of FIGURE 44;

FIGURE 46 is an enlarged cutaway view of FIGURE 44 as the reset feature is being engaged;

FIGURE 47 is a perspective view of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 48 is a perspective view of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 49 is a cutaway view of FIGURE 48;

FIGURE 50 is a cutaway view of FIGURE 48 with the stylet being withdrawn from the outer needle;

FIGURE 51 is an enlarged view of a stylet handle shown in FIGURE 48;

FIGURE 52 is a perspective view of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 53 is a perspective view of an adjustment feature of a particular embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 54 is a perspective view of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 55 is an enlarged perspective view of a depth stop of the apparatus shown in FIGURE 54;

FIGURE 56 is a cutaway view of the depth stop shown in FIGURE 55;

FIGURE 57 is an enlarged view of a binding member of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 58 is an enlarged view of the binding member shown in FIGURE 57 in the binding position;

FIGURE 59 is an enlarged view of the binding member shown in FIGURE 57 with a resetting piece disengaged from the binding member;

FIGURE 60 is an enlarged view of the binding member shown in FIGURE 57 with the resetting piece engaging the binding member;

FIGURE 61 is a perspective view of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 62 is a perspective view of the embodiment shown in FIGURE 61 having the depth stop partially advanced down the needle;

FIGURE 63 is a perspective view of an obturator incorporating an integral funnel guide and reset feature;

FIGURE 64 is a perspective view of the embodiment shown in FIGURE 63 during resettable engagement;

FIGURE 65 is a cutaway view of the embodiment shown in FIGURE 64;

FIGURE 66 is an enlarged cutaway view of the embodiment shown in FIGURE 64;

FIGURE 67 is a perspective view of the embodiment shown in FIGURE 64 with an obturator inserted through the needle;

FIGURE 68 is a cutaway view of the embodiment shown in FIGURE 67;

FIGURE 69 is an enlarged cutaway view of FIGURE 68;

FIGURE 70 is a perspective view of an obturator;

FIGURE 71 is a perspective view of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 72 is a cutaway view of the safety shield shown in FIGURE 71;

FIGURE 73 is an enlarged cutaway view of FIGURE 72;

FIGURE 74 is an enlarged cutaway view of FIGURE 72;

FIGURE 75 is a perspective view of a funnel for guiding an obturator;

FIGURE 76 is a cutaway view of a funnel placed over a needle;

FIGURE 77 shows locating features on the safety shield for guiding the obturator to the inner diameter of the needle;

FIGURE 78 shows an obturator inserted into a funnel;

FIGURE 79 is a perspective view of an alternative embodiment of the medical needle shield apparatus according to the present disclosure;

FIGURE 80 is a cutaway view of the embodiment shown in FIGURE 79;

FIGURE 81 is an enlarged view of the safety shield of the embodiment shown in FIGURE 79;

FIGURE 82 is a cutaway view of the safety shield having a needle inserted;

FIGURE 83 is a perspective view of the safety shield having an obturator inserted;

FIGURE 84 is an enlarged perspective view of the safety shield having an adjustable guide;

FIGURE 85 is an enlarged perspective view of the safety shield having an adjustable guide with a reset area;

FIGURE 86 is a guiding member integrated with an obturator;

FIGURE 87 is a guiding member integrated with an obturator having a spring;

FIGURE 88 is an enlarged view of the guiding member shown in FIGURE 87;

FIGURE 89 is an obturator handle having a resettable feature;

FIGURE 89 is an obturator handle having a resettable feature;

FIGURE 90 is an obturator handle having a resettable feature inserted into a needle;

FIGURE 91 is an alternative embodiment of the medical needle shield apparatus according to the present disclosure; and

FIGURE 92 is an alternative embodiment of the medical needle shield apparatus according to the present disclosure.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS

The exemplary embodiments of the medical needle shield apparatus and methods of operation disclosed are discussed in terms of medical needles for infusion of intravenous fluids, medication infusion or fluid collection, guiding of other needles, e.g., biopsy, and more particularly, in terms of needle shield apparatus employed with a needle cannula that prevent hazardous exposure to the needle tip, including, for example, inadvertent needle sticks. It is envisioned that the present disclosure, however, finds application to a wide variety of cannula needles and devices for the infusion of preventive medications, medicaments, therapeutics, etc. to a subject, such as, for example, epidural needles, spinal needles, biopsy needles, chiba needles, potts cournand needles, coaxial introducer needles, Y-sites, etc. It is also envisioned that

the present disclosure may be employed for collection of body fluids and/or tissues, including those employed during procedures relating to soft tissue biopsy, bone biopsy, phlebotomy, digestive, intestinal, urinary, veterinary, etc. It is contemplated that the medical needle shield apparatus may be utilized with other medical needle applications including, but not limited to, fluid infusion, fluid collection, catheters, catheter introducers, guidewire introducers, biopsy needle introducers, spinal and epidural, biopsy, aphaeresis, dialysis, blood donor, Veress needles, Huber needles, etc.

In the discussion that follows, the term "proximal" refers to a portion of a structure that is closer to a clinician, and the term "distal" refers to a portion that is further from the clinician. As used herein, the term "subject" refers to a patient that receives infusions or has blood and/or fluid collected therefrom using the medical needle shield apparatus. According to the present disclosure, the term "clinician" refers to an individual administering an infusion, performing fluid or tissue collection, installing or removing a needle cannula from a medical needle shield apparatus and may include support personnel.

The following discussion includes a description of the medical needle shield apparatus, followed by a description of the method of operating the medical needle shield apparatus in accordance with the present disclosure. Reference will now be made in detail to the exemplary embodiments of the disclosure, which are illustrated in the accompanying figures.

Turning now to the figures, wherein like components are designated by like reference numerals throughout the several views. Referring initially to FIGURES 1-11, there is illustrated a medical needle shield apparatus, constructed in accordance with the principals of the present disclosure. The medical needle shield apparatus includes a shield 101 that is extensible from a retracted position (FIGURES 1, 3) to an extended position (FIGURES 2, 4) to enclose a distal end 115 of a needle such as, for example, stylet 106 of a needle assembly. The needle assembly includes a hollow outer needle 103. Stylet 106 is slideably and concentrically disposed with needle 103 for employment therewith during a medical needle application, as will be discussed. A stylet handle 113 is connected to stylet 106 to facilitate manipulation thereof. Other needle assemblies are also contemplated, including for example, needle cannulae, guide wire/introducers, etc.

A binding member 105 is disposed within shield 101 and defines binding surfaces 122. Binding surfaces 122 form an aperture configured for slidable receipt of stylet 106 between the retracted position and the extended position. Binding member 105 includes a drag inducing member, such as, for example, friction members 126 extending therefrom. Binding member 105 has a stylet communicating surface 123 that is engageable with stylet 106 to prevent rotation to the binding position of binding member 105.

Friction members 126 are configured for slidable engagement with stylet 106 between the retracted position and the extended position such that friction members 126 engage stylet 106 to create a drag force with stylet 106. It is envisioned that one or a plurality of friction members 126 may be employed.

The drag force in conjunction with one of blocking members 116 and/or 117, cause binding member 105 to move to a binding position (FIGURE 4). The force created by blocking members 116 and/or 117 acts in a direction opposite to the drag force. This causes a force couple, which moves binding member 105 to the binding position.

As stylet 106 is released from engagement with a stylet communicating surface 123, binding member 105 and a retainer 114 move to the binding position. Rotation of binding member 105 is no longer opposed by engagement with stylet 106 at stylet communicating surface 123. Thus, binding member 105, with retainer 114, is subject to inclination into the binding position. Rotation of binding member 105 causes binding surfaces 122 to frictionally engage stylet 106 to prevent movement thereof.

Blocking members 116 and/or 117 cause binding member 105 to move to the binding position as forces imposed on shield 101 cause relative movement thereof in either direction along longitudinal axis *x*. This maintains stylet 106 within shield 101 to avoid hazardous exposure to distal end 115. It is envisioned that stylet communicating surface 123 may include ribs, projections, cavities, etc. for engagement with stylet 106 or that a portion of stylet communicating surface 123 engages stylet 106.

The components of the medical needle shield apparatus can be fabricated from a material suitable for medical applications, such as, for example, polymerics or metals, such as stainless steel, depending on the particular medical application and/or

preference of a clinician. Semi-rigid and rigid polymerics are contemplated for fabrication, as well as resilient materials, such as molded medical grade polypropylene. However, one skilled in the art will realize that other materials and fabrication methods suitable for assembly and manufacture, in accordance with the present disclosure, also would be appropriate.

In an illustrative embodiment, shield 101 includes a bearing 102 that houses binding member 105. Bearing 102 may be monolithically formed or integrally assembled of multiple sections and may be substantially transparent, opaque, etc.

In the retracted position, shield 101 is disposed adjacent to a needle hub 104 of outer needle 103. It is contemplated that outer needle 103 may also be comprised of a flexible, polymeric material, and that the components of the medical needle apparatus may be employed with other needle applications, such as, for example, catheters, PICC introducers, etc.

Binding member 105 may be monolithically formed and includes an aperture plate 118, frictional members 126, end sensing member 119, stylet communicating surface 123, binding member reset surface 107 and retainer 114. It is contemplated that binding member 105 may include one or more frictional members 126, and that retainer 114 may extend from bearing 102. Aperture plate 118 may have a rectangular, generally planar configuration with sufficient stiffness to produce forces for binding stylet 106, as will be discussed. It is envisioned that aperture plate 118 may have an arcuate surface, undulating, etc. It is further envisioned that aperture plate 118 may have various degrees of stiffness according to the requirements of a particular application.

The embodiment of a resettable passive safety device disclosed in FIGURES 1-11 show a hollow needle 103 solid stylet 106, rotational housing with a stylet shield 125 and thrust bore 133, a bearing 102 with thrust collar 132, and a binding member 105. The thrust bore 133 and thrust collar 132 are configured to allow rotation of stylet shield 125 relative to bearing 102.

The resettable feature of this device is employed after the passive safety device has been activated. Initially, the safety shield 101 and needle 103 are positioned over the stylet 106 (FIGURE 1). During the medical procedure, the stylet 106 is automatically protected by the safety shield 101 as the stylet 106 is withdrawn from the needle (FIGURE 2).

The safety shield 101 is advanced to near the distal end of the stylet 115 in a position prior to activation of the binding member 105 (FIGURE 3). In this position, the hub retainer 114 retains the proximity of the needle hub 104 to the safety shield 101 by interacting with hub slot 124 and the binding member 105 is in the sliding orientation. It is envisioned that hub slot 124 may be in the form of other shapes for providing a cavity.

In FIGURE 4, the safety shield 101 is positioned further toward the distal end of the stylet 115 to the point where the safety shield 101 is activated. The binding member 105 has moved to the binding orientation and the hub retainer 114 of the binding member 105 has released the needle hub 104.

In FIGURE 2, the activated and locked safety shield 101 is illustrated. In this configuration, the needle 103 has been removed, the stylet distal end 115 is inside the housing at a distance which prevents human contact, and the binding member 105 is in the binding orientation.

Frictional members 126 may be monolithically formed with binding member 105 and extend from aperture plate 118 in association therewith for alignment with aperture 138 and engagement with stylet 106. Such engagement creates a frictional drag force with stylet 106. This frictional drag force in conjunction with one of the blocking members 116 and/or 117 causes binding member 105 to move with stylet 106, which generates a rotating force and inclination of aperture plate 118. The rotating force and inclination urge rotation of binding member 105. It is contemplated that a single friction member may be employed. It is further contemplated that frictional members 126 may have flexible portions, which may be of varying flexibility according to the particular requirements of a needle application.

As facilitated by movement of stylet 106, the canting force causes a lever or moment of end sensing member 119, which is opposed to prevent rotation of binding member 105. The canting force is opposed by engagement of stylet communicating surface 123 with stylet 106 in a non-binding or sliding orientation (FIGURE 3) of binding member 105.

End sensing member 119 extends distally from aperture plate 118. End sensing member 119 may be perpendicularly oriented relative to a plane defined by aperture plate 118. This perpendicular orientation facilitates inclination of aperture plate 118 for disposal in a binding or non-binding orientation of binding member 105.

It is envisioned that end sensing member 119 may be variously oriented with aperture plate 118 and may flexibly extend therefrom.

Stylet communicating surface 123 opposes the canting force of end sensing member 119 directed to stylet 106. The canting force is generated by friction members 126 in conjunction with one of blocking members 116 and/or 117 and facilitates inclination of aperture plate 118. Inclination, however, is prevented in the non-binding or sliding orientation because of the engagement of stylet communicating surface 123 with stylet 106. As stylet 106 is retracted proximally and shield 101 is extended distally, stylet 106 continues to slideably engage stylet communicating surface 123.

As stylet 106 is released from engagement with stylet communicating surface 123, as shown in FIGURE 4, a drag force is created between friction members 126 and stylet 106. The drag force in conjunction with blocking member 116, cause aperture plate 118 to move to the binding position, as discussed.

Rotation of aperture plate 118 causes binding surfaces 122 to frictionally engage stylet 106 to prevent movement thereof. Blocking members 116, 117 cause aperture plate 118 to move to the binding position as forces are imposed on shield 101 in either direction along longitudinal axis x. This maintains stylet 106 within shield 101 to avoid hazardous exposure to distal end 115.

Aperture 138 is formed within aperture plate 118 for slidable engagement with stylet 106 during movement between the retracted position and the extended position of shield 101. Aperture 138 includes binding surfaces 122 formed on opposing sides of aperture 138 that engage stylet 106 to prevent movement thereof in the extended position of shield 101. It is contemplated that engagement to prevent movement of stylet 106 may include penetrating, frictional, interference, etc. It is envisioned that aperture 138 may have various geometric configurations, such as radial, polygonal, etc. It is further envisioned that aperture 138 may define an open cavity within aperture plate 118, such as, for example, "U" shaped and open to one or a plurality of edges of aperture plate 118.

The inclination of aperture plate 118 relative to longitudinal axis x facilitates sliding and binding, via binding surfaces 122, of stylet 106 within shield 101 to prevent hazardous exposure to distal end 115. For example, as shown in FIGURE 3, aperture plate 118 is oriented at an angle of approximately 90° relative to longitudinal

axis x such that aperture plate 118 is disposed substantially perpendicular to stylet 106. In this non-binding or sliding orientation, stylet 106 is free to slide within aperture 138. As stylet 106 is retracted and shield 101 is extended, stylet 106 continues to engage stylet communicating surface 123 and aperture plate 118 maintains its perpendicular orientation relative to longitudinal axis x.

Referring to FIGURE 4, shield 101 is manipulated such that friction members 126 in conjunction with blocking member 116 cause binding member 105 to rotate relative to longitudinal axis x. Aperture plate 118 rotates out of perpendicular alignment with stylet 106 such that aperture plate 118 is oriented at an angle less than 90° with respect to longitudinal axis x.

As aperture plate 118 rotates, the binding member 105 approaches a binding orientation. The binding orientation includes engagement of binding surfaces 122 with stylet 106 due to the binding orientation of aperture plate 118. This engagement creates binding frictional forces on stylet 106, in conjunction with frictional members 126 and blocking members 116, 117 to prevent movement of stylet 106 relative to shield 101 in both distal and proximal directions, and to maintain distal end 115 within shield 101 to prevent hazardous exposure thereto.

Blocking members 116, 117 are disposed not to interfere with stylet 106. Blocking members 116, 117 define surfaces that facilitate disposal of aperture plate 118 in a binding orientation.

For example, as shown in FIGURE 3, shield 101 is in a retracted position and stylet 106 is fully extended. Binding member 105 and aperture plate 118 are in a non-binding or sliding orientation such that aperture plate 118 is substantially perpendicular to longitudinal axis x. Blocking members 116, 117 may engage aperture plate 118 to maintain aperture plate 118 in the perpendicular orientation. Blocking members 116, 117 may also maintain such orientation during extension of stylet 106 or may not engage stylet 106.

As stylet 106 is retracted and shield 101 is extended, as shown in FIGURE 4, friction members 126 create a drag force via engagement with stylet 106 on binding member 105 and in conjunction with blocking member 116 cause aperture plate 118 to rotate in a counter-clockwise direction to the binding position. Blocking members 116, 117 engage aperture plate 118 to facilitate rotation thereof from the

perpendicular position into the binding position such that binding surfaces 122 engage stylet 106, as discussed. This configuration prevents movement of stylet 106.

Binding of binding member 105 to stylet 106 is facilitated by the friction force generated between binding surfaces 122 and stylet 106. This frictional engagement prevents axial movement of stylet 106 relative to bearing 102 when shield 101 is in the extended position. This configuration advantageously prevents hazardous exposure to stylet 106. It is contemplated that binding surfaces 122 may include sharp edges to increase frictional engagement. It is further contemplated that the binding friction force may be created and varied by one or more altering factors, such as, for example, aperture 138 configuration and dimension, stylet 106 configuration and dimension, aperture plate 118 thickness, the dimension from blocking members 116, 117 contact point to the centerline of stylet 106 and the coefficient of friction between aperture 138 and stylet 106 depending on the particular requirements of a needle application. It is envisioned that friction members 126 may be configured so as to vary the drag force with variation of the inclination of the aperture plate 118, this variation in drag force may be accomplished by geometric changes in the shape of the friction members 126, such as wedge shapes or the inclusion of notches to engage stylet 106, this variation in drag force may also be accomplished through the selective application of friction modifying materials or coatings such as oils, jells, greases, or coatings which change the friction.

It is envisioned that the aperture in aperture plate 118 may create a drag force via engagement with sylet 106 to cause rotation of binding member 105, similar to that described. It is further envisioned that materials such as, for example, jells, greases, etc. may be employed to create a frictional drag force with stylet 106 to cause rotation of binding member 105.

Needle hub 104 is mounted with needle 103 and is releasably mounted with shield 101 via releasable engagement with retainer 114. Needle hub 104 is employed with the medical needle shield apparatus of the present disclosure for various utility according to the requirements of a particular medical needle application. Shield 101 and needle hub 104 slidably support needle 103 and stylet 106 for use thereof. Handle 113 facilitates manipulation thereof.

Needle hub 104 has a hub slot 124 for receipt and engagement with binding member 105. Needle hub 104 has a finger tab 160 for urging needle hub 104 in a

direction, along longitudinal axis x, away from shield 101. This configuration facilitates removal and use of needle hub 104 and needle 103 from shield 101 during a medical needle application. It is contemplated that finger tab 160 may be alternatively configured and dimensioned according to the needle application.

A flange 162 of needle hub 104 is concentrically supported by a control surface 110 disposed about an inner surface of bearing 102. Control surface 110 engages an outer surface 164 of flange 162 for releasable support thereof. Outer surface 164 may engage control surface 110 in a frictional, interference, etc. fit to maintain releasable positioning with bearing 102. It is contemplated that control surface 110 may engage other portions of needle hub 104.

Bearing 102 includes hub stop surfaces 112 that facilitate positioning of needle hub 104 with bearing 102. Hub stop surfaces 112 prevent proximal movement of needle hub 104 during mounting with and relative to bearing 102. Hub stop surfaces 112 advantageously facilitate control of the degree of insertion with bearing 102 according to the requirements of a particular medical needle application. One or a plurality of hub stop surfaces 112 may be employed. It is contemplated that hub stop surfaces 112 may include springs, clips, etc. to facilitate attachment with needle hub 104.

Retainer 114 may extend transversely from a distal end of stylet communicating surface 123. Hub retainer 114 extends a sufficient length for corresponding receipt within hub slot 124 of needle hub 104. In association with a non-binding or sliding orientation of binding member 105, retainer 114 engages needle hub 104, in hub slot 124, for releasably mounting with bearing 102 of shield 101.

As stylet 106 is retracted in a proximal direction and shield 101 is extended in a distal direction, retainer 114 rotates in a counter clockwise direction (FIGURE 4) relative to longitudinal axis x due to the canting forces generated by friction members 126. Retainer 114 disengages from hub slot 124 to release needle hub 104 from bearing 102. A clinician may manipulate finger tab 160 to manipulate needle hub 104 distally and apart from shield 101. It is contemplated that retainer 114 may be variously oriented from binding member 105 or stylet communicating surface 123. It is further contemplated that hub slot 124 may be variously dimensioned to extend

about the circumference of needle hub 104. Hub slot 124 may include tabs, etc. for retention with retainer 114.

To re-access the stylet distal end 115 using the resettable passive safety device, the stylet shield 125 is brought to mate concentrically with the proximal end of the needle hub 104, in a similar fashion to the pre-activated state of the device. As this occurs, the binding member reset surface 107 comes into contact with the reset surface 108. This action is depicted in the embodiment shown in FIGURE 10.

As the stylet 106 is advanced from a proximal-to-distal direction, the reset surface 108 deflects the binding member reset surface 107, along with the end sensing member 119, to a position above the stylet 106 surface and urges the binding member 105 from the binding orientation to the sliding orientation. With the binding member 105 in the sliding orientation, the stylet 106 becomes free to advance into the needle 103.

Concurrently, due to the contact between the reset surface 108 and the binding member reset surface 107, the hub retainer 114 is urged into the hub slot 124. This causes the hub retainer 114 of the binding member 105 to again retain the needle hub 104 to the safety shield 101 through the interaction with the hub slot 124 (FIGURE 11).

Upon being reset, the safety shield 101 and needle 103 are positioned over the stylet 106, as seen in FIGURE 1. During the medical procedure, the stylet 106 will be automatically protected by the safety shield 101 as the stylet 106 is again withdrawn from the needle.

FIGURES 12 – 15 illustrate the resettable safety shield according to the present disclosure as applied to a needle with a luer fitting 121 and a luer taper 109. In this embodiment, the reset surface 108 is provided on a portion separate from the needle hub 104. A reset surface spring 111 exerts a force to bias the reset surface 108 in the proximal direction. The reset surface spring 111 can be made from any number of suitable resilient materials commonly known, including metal, plastic, elastomeric materials, and the like.

In the embodiment wherein the reset surface 108 is within the luer fitting 121, the reset surface spring 111 assures that the reset surface 108 is in the correct location in the needle hub to provide alignment and engagement between the reset surface 108 and binding member reset surface 107. The spring 111 may be comprised of a

resilient material such as rubber, urethane, etc. When a luer male taper, such as for example, a luer lock or luer slip is inserted into needle hub 104, the reset surface spring 111 is compressed and the reset surface 108 is displaced to allow the luer male taper to mate with the entire length of luer taper 109. It is envisioned that the reset surface 108 may also be disposed around the luer fitting 121, as shown in FIGURE 23B. The embodiment shown in FIGURE 23B also shows an alternate embodiment of the reset surfaces 107 extending from the binding member 105 and engaging retaining surface 141.

To re-access the stylet distal end 115 using the resettable passive safety device, the stylet shield 125 is brought to mate concentrically with the proximal end of the needle hub 104, in a similar fashion to the pre-activated state of the device. As this occurs, the binding member reset surface 107 comes into contact with the reset surface 108. This action is depicted in the embodiment shown in FIGURE 14.

As the stylet 106 is advanced from a proximal-to-distal direction, the reset surface 108 deflects the binding member reset surface 107, along with the end sensing member 119, to a position above the stylet 106 surface and urges the binding member 105 from the binding orientation to the sliding orientation. With the binding member 105 in the sliding orientation, the stylet 106 becomes free to advance into the needle 103.

Concurrently, due to the contact between the reset surface 108 and the binding member reset surface 107, the hub retainer 114 is urged into the hub slot 124. This causes the hub retainer 114 of the binding member 105 to again retain the needle hub 104 to the safety shield 101 through the interaction with the hub slot 124 (FIGURE 15).

Upon being reset, the safety shield 101 and needle 103 are positioned over the stylet 106. During the medical procedure, the style 106 will be automatically protected by the safety shield 101 as the stylet 106 is again withdrawn from the needle. The safety shield 101 may incorporate a snap fit to the hub (not shown) to further facilitate engagement.

FIGURES 16-27 illustrate the resettable safety shield according to the present disclosure as applied to a bone biopsy needle 101. In this embodiment, the luer taper 109 is used in the manner described hereinbefore with respect to FIGURES 12 – 15. The bone biopsy needle 101 may also include an adjustable depth stop assembly 140

for setting the desired needle 103 insertion depth. A lock nut 142 locks the depth stop assembly 140 in the desired position. Tabs 144 engage corresponding slots 156 (shown in FIGURE 25) to fix depth stop assembly 140 while the lock nut 142 is engaged.

A needle shield 137 may be disposed in depth stop assembly 140 as illustrated in FIGURE 17. Corresponding threads 148 and 150 disposed on depth stop assembly 140 and sleeve 151, respectively, provide for threadable movement of depth stop assembly 140. Needle shield 137 operates in similar fashion to shield 101 described in FIGURES 1-11, as will be discussed in more detail hereafter.

The medical needle shield apparatus for stylet 106 includes a binding member 105 that is disposed within a stylet shield 125, similar to that described with regard to FIGURES 1-11, that is extensible from a retracted position to an extended position to enclose a distal end of a stylet 106 of a needle assembly. Stylet 106 is slideably and concentrically disposed with a needle 103 of the needle assembly for employment therewith during a bone biopsy needle application. A stylet handle 113 is connected to stylet 106.

In operation, the clinician (not shown) manipulates handle 113 such that shield 101 is in the retracted position (FIGURES 16, 18, 19) and binding member 105 is in a non-binding or sliding position. Handle 113 may include a tab 152 for temporary securement to hub 104. Hub 104 includes an opening (not shown) such that handle 113 may be released from temporary securement as tab 152 is rotated to align tab 152 with the opening. Stylet 106 is extended relative to shield 101 such that needle hub 104 is disposed about needle 103 and needle hub 104 is releasably mounted with bearing 102. A procedure employing the medical needle shield apparatus with stylet 106 and needle 103 is performed by the clinician to completion.

Needle hub 104 is releasably mounted with stylet handle 113. Referring to FIGURE 22, stylet 106 is retracted proximally such that shield 101 is extended to the extended position and binding member 105 is disposed in a binding position. Needle hub 104 is released from stylet shield 125 in the extended position. This maintains stylet 106 within stylet shield 125 to avoid hazardous exposure to the distal end of stylet 106.

To re-access the stylet distal end 115 using the resettable passive safety device, the stylet shield 125 is brought to mate concentrically with the proximal end

of the needle hub 104, in a similar fashion to the pre-activated state of the device. As this occurs, the binding member reset surface 107 comes into contact with the reset surface 108. This action is depicted in the embodiment shown in FIGURE 23A.

As the stylet 106 is advanced from a proximal-to-distal direction, the reset surface 108 deflects the binding member reset surface 107, along with the end sensing member 119, to a position above the stylet 106 surface and urges the binding member 105 from the binding orientation to the sliding orientation. With the binding member 105 in the sliding orientation, the stylet 106 becomes free to advance into the needle 103.

Concurrently, due to the contact between the reset surface 108 and the binding member reset surface 107, the hub retainer 114 is urged into the hub slot 124. This causes the hub retainer 114 of the binding member 105 to again retain the needle hub 104 to the safety shield 101 through the interaction with the hub slot 124.

Upon being reset, the stylet shield 125 and needle 103 are positioned over the stylet 106, as seen in FIGURE 16. During the medical procedure, the stylet 106 will be automatically protected by the stylet shield 125 as the stylet 106 is again withdrawn from the needle.

FIGURE 24 illustrates a syringe inserted into hub 104 for aspiration purposes with stylet 106 removed.

FIGURE 25 illustrates the resettable safety shield device 101 with the depth stop assembly 140 removed and the needle shield 137 in the retracted position. FIGURES 26-27 show the needle shield 137 in the shielded configuration. A binding member 105' is disposed within needle shield 137 and defines binding surfaces (not shown). Binding surfaces form an aperture configured for slidable receipt of hollow needle 103 between the retracted position and the extended position. Binding member 105' includes a drag inducing member, such as, for example, friction members 126' extending therefrom. Binding member 105' has a needle communicating surface 123' that is engageable with hollow needle 103 to prevent rotation of binding member 105'.

Friction members 126' are configured for slidable engagement with hollow needle 103 between the retracted position and the extended position such that friction members 126' engage hollow needle 103 to create a drag force with hollow needle

103. It is envisioned that one or a plurality of friction members 126' may be employed.

The drag force in conjunction with one of blocking members 116' and/or 117', cause binding member 105' to move to a binding position (FIGURE 27). The force created by blocking members 116' and/or 117' acts in a direction opposite to the drag force. This causes a force couple, which moves binding member 105' to the binding position.

A funnel portion 146 in needle shield 137 acts as a obturator guide to facilitate insertion of a obturator or the like. Depth stop 140 may be slideably removed with safety shield 137 remaining in the proximal position. This allows a clinician to utilize the entire length of needle 103. As shown, depth stop 140 is removed prior to activation of safety shield 137. Alternatively, safety shield 137 may be connect to, or formed as part of, the depth stop 140.

FIGURES 28-29 illustrate the resettable safety shield device according to the present disclosure as applied to a PICC introducer or similar catheter and needle introducers. In this embodiment, the hollow needle 103 is polymeric, and the stylet (or inner needle) 106 is a sharp, hollow bore cannula. The handle 113 of the PICC Introducer has a flash plug 135 and a flash chamber 136 that is in communication with inner needle 106. A luer fitting 121 communicates with the flash chamber 136 and allows the fitting of other medical devices.

The medical needle shield apparatus includes a shield 101, similar to those described, that is extensible from a retracted position (FIGURE 28) to an extended position (FIGURES 31-32) to enclose a distal end of hollow needle 103 of a needle assembly. Hollow needle 103 is slideably and concentrically disposed with a hub 104 (FIGURE 28) of the needle assembly for employment therewith during a PICC introducer application. Hub 104 may, or may not, be splitable. Hub 104 is desirably fabricated from a polymeric material. It is contemplated that the medical needles of the present disclosure may incorporate a protective needle sheath member to facilitate additional protection during transportation and use of the medical needles.

A handle 113 is connected to inner needle 106. Handle 113 may have a flash chamber 139 in communication with inner needle 106. A luer fitting 121 communicates with flash chamber 139 that facilitates connection to various medical devices via either a luer slip or luer lock attachment feature.

A binding member 105, similar to that described with regard to FIGURES 1-11, is disposed within shield 101. Shield 101 includes a bearing 102 that houses binding member 105.

Needle hub 104 is mounted with hollow needle 103. Needle hub 104 is releasably mounted with shield 101 via releasable engagement with a retainer 114 of binding member 105. Needle hub 104 has a hub slot 124 for receipt and engagement with binding member 105. This configuration facilitates removal and use of hub 104 from shield 101 during a medical needle application.

A flange of needle hub 104 is concentrically supported by a control surface of a stylet shield 125, discussed below. The control surface engages the flange for releasable support thereof. Retainer 114 extends for receipt within a hub slot 124 of needle hub 104. In association with a non-binding or sliding orientation of binding member 105, retainer 114 is disposed within hub slot 124 for releasably mounting with shield 101. As inner needle 106 is retracted and shield 101 is extended, retainer 114 rotates in a counter clockwise direction and disengages from hub slot 124 to release needle hub 104 from stylet shield 125.

A stylet shield 125 is disposed for rotation and enclosure of the distal end of inner needle 106. Stylet shield 125 is mounted with handle 113 and freely rotates relative to shield 101 and inner needle 106 in the extended position of shield 101. Relative rotation of stylet shield 125 is facilitated by support at bearing openings formed in stylet shield 125 and axles, similar to those described above. In a binding position, the bearing configuration supports rotation of stylet shield 125 relative to shield 101 and inner needle 106.

Inner needle 106 is retracted proximally such that shield 101 is extended to the extended position and binding member 105 is disposed in a binding position. Needle hub 104 is released from shield 101 and shield 101 encloses the distal end of needle 103 in the extended position. This maintains needle 103 within shield 101 to avoid hazardous exposure to the distal end of needle 103.

In operation, needle hub 104 is released from shield 101 and a stylet shield 125 encloses the distal end of inner needle 106 in the extended position, as described above. This maintains inner needle 106 within shield 101 to avoid hazardous exposure to the distal end thereof.

To re-access the inner needle 106 using the resettable passive safety device, the stylet shield 125 of the rotating focusing is brought to mate concentrically with the proximal end of the needle hub 104, in a similar fashion to the pre-activated state of the device. As this occurs, the binding member reset surface 107, on the end sensing member 119, comes into contact with the reset surface 108. This action is depicted in the embodiment shown in FIGURES 30 and 33.

As the inner needle 106 is advanced from a proximal-to-distal direction, the reset surface 108 deflects the binding member reset surface 107, along with the end sensing member 119, to a position above the inner needle 106 surface and urges the binding member 105 from the binding orientation to the sliding orientation. With the binding member 105 in the sliding orientation, the inner needle 106 becomes free to advance into hollow needle 103.

Concurrently, due to the contact between the reset surface 108 and the binding member reset surface 107, the hub retainer 114 is urged into the hub slot 124. This causes the hub retainer 114 of the binding member 105 to again retain the needle hub 104 to the safety shield 101 through the interaction with the hub slot 124.

Upon being reset, the safety shield 101 and hollow needle 103 are positioned over the inner needle 106, as seen in FIGURE 28. During the medical procedure, the inner needle 106 will be automatically protected by the safety shield 101 as the inner needle 106 is again withdrawn from the needle.

FIGURES 34-37 illustrate the resettable safety shield device according to the present disclosure as applied to a port access device or implanted pump. It is contemplated herein that the port access device may be implanted or exterior to a patient. Operation and construction of this embodiment is in accordance with the various embodiments described herein such as for example the embodiments disclosed in FIGURES 1-11. FIGURES 34 – 37 show an implanted port 127 and skin layer 129 along with an implanted port access body 130. The port access body contains the reset surface 108. In the present embodiment, the stylet 106 is protected by the safety shield 101 before use. Reset surface 108 and binding member reset surface 107 reset the safety device as described hereinbefore to allow stylet 106 to pass through the skin layer 129 and enter the implanted port 127. The safety shield device reactivates upon removal of stylet 106 from the implanted port access body 130.

With reference to FIGURES 38-41, illustrated is a resettable safety shield device according to the present disclosure as applied to a drug vial access. Operation and construction of this embodiment is in accordance with the various embodiments described herein such as for example the embodiments disclosed in FIGURES 1-11. FIGURES 38 – 41 show a drug vial 131 along with a corresponding drug vial access body 134. Stylet 106 is protected by a safety shield 101 before use. Reset surface 108 engages binding member reset surface 107 to allow stylet 106 to enter drug vial 131. The safety device re-activates upon removal of stylet 106 from drug vial access body 134.

Referring to FIGURES 42-46, there is illustrated another embodiment of the medical needle shield apparatus having a resettable feature, constructed in accordance with the principals of the present disclosure.

Reset element 201 may be part of, but is not limited to, the following: the hub/handle 203, inner housing 202, outer housing 204, binding member 205, or may be a separate piece that interacts with any of the above pieces. The reset element 201 may contain reset surfaces 206 that are intended to interact with the binding member 207. When the reset element 201 is active, the reset surfaces 206 interact with the binding member 207 to cause the binding on the stylet 208 to be unlocked. If the reset element 201 is a part of the binding member 207, the reset surfaces 206 may extend from the binding member 207 and may be directly linked so that the activation of the reset element 201 will unlock the binding of binding member 205 to the stylet 208.

It is desirable that the reset element 201 be inactive, meaning that the device cannot be accidentally reset. It is also desirable to design the reset element 201 such that an intentional effort must be made to activate the reset element 201 and to reset the device. Therefore, it may be desirable that the reset element 201 be capable of toggling between active and inactive states. This may be accomplished in many ways which include, but are not limited to, hinges, cantilevered beams, bi-stable mechanisms, springs, etc.

In order to activate the reset element 201, an intentional effort must be made which may require the reset element 201 to interact with reset geometry 209 that has been brought into a position to reset the device. As illustrated in FIGURES 3-5, the reset geometry 209 may be disposed on a hub/handle 210. This reset geometry 209 may include a luer on a hub/handle, a separate piece containing reset geometry, and

geometry on a tray. However, the reset geometry 209 is not limited to a geometry on any apparatus intended to interact with the reset element 201 to reset the safety shield 212.

It may also be desirable to incorporate a retention element 211. In many cases it is desirable to have the safety shield 212 retained in some manner until the safety shield 212 is bound to the stylet 208. In the embodiment shown in FIGURES 44-46, the shield 212 is retained to a hub/handle 210. In this configuration, the safety shield 212 is retained until the stylet 208 is removed at which time the safety shield 212 senses the end of the stylet 208 and binds to the stylet 208. This embodiment depicts the retention element 211 as a detent arrangement, which allows the safety shield 212 to be retained to the hub/handle 210. The retention element 211 may also include, but is not limited to, a snap, latch, hook, friction, etc.

Referring to FIGURES 47-51, in certain procedures it is necessary to retain the stylet handle 221 to the main device handle 222. Previous retention elements included detents and bayonet style retention. These methods may cause abrupt forces upon removal, which can lead to device misplacement or further pain to the patient. These retention methods may also fail due to the high forces of rotational movement experienced during a procedure.

The embodiment shown in FIGURES 47-51 illustrates retention with a snap arrangement 223. This allows for a robust retention to the main device handle 222. It snaps 225 securely in place and resists rotational movement as well as axial movement. The snap arrangement 223 may also have a button/lever 226, or other similar snap arrangement, to release the snap 225 engagement. This allows for no abrupt forces upon removal and an easy one-handed release.

Referring to FIGURES 52-60, a depth stop 231 may be required in certain procedures. Depth stops 231 often have an adjustment feature 232. As shown in FIGURE 53, the adjustment feature 232 may include, but is not being limited to, threads 234. In such instances, the safety shield 233 may contain an adjustment feature 232 such as threads 234 to advance the depth stop 231. The safety shield 233 may also have depth indicators 235 to indicate the depth of the depth stop 231. The safety shield 233 may also include a retainer 236 for the depth stop 231. The retainer 236 may include, but is not limited to, detents, hooks, friction, etc. The depth stop 231 may also be a means of activating the safety shield 233.

Another embodiment is shown in FIGURE 54, illustrating the safety shield 233 with a depth stop 231 having an adjustment feature 232. The adjustment feature 232 may be similar to those mentioned above. The depth stop 231 may have a retainer 236 similar to that mentioned above. The retainer 236 may also serve the function of a safety shield detent as well. One embodiment also includes a lock nut 237 that can be used in conjunction with depth stop 231 and thread 234 (see FIGURE 52).

Referring to FIGURES 57 and 58, for certain procedures it may be necessary to introduce an apparatus 240, such as a guide wire, catheter, etc., through a needle 238. In these circumstances it may also be desirable to activate a safety shield 233 to protect the sharp 239, while the apparatus 240 remains in the needle 238. One embodiment includes a dual end sensing member 241. This type of end sensing member allows for full function of the device with an apparatus 240 through the needle 238. The dual end sensing member 241 is positioned to slide along the needle 238, thus preventing binding of the binding member 242. The dual end sensing member 241 can also be positioned to slide on the outer rim of the needle 238. In this position, the dual end sensing member 241 continues to sense the end of the needle 238. However, as the binding member 242 passes through to its binding state, the dual end sensing member 241 can pass around any apparatus 240 disposed in the needle 238.

Another application of the dual end sensing member 241 is for resetting applications. In some resetting cases, the end sensing member is lodged underneath the needle 238. This may cause the device to not be resettable. A dual end sensing member 241 may be forced around the needle 238 by a resetting piece 243 while being reset. The dual end sensing member 241 may be flexible enough to go around the needle 238 when resetting is occurring, yet be rigid enough to not slip around the needle 238 during normal use. This may require a balance of forces. A dual end sensing member 241 may also activate on a needle taper.

FIGURES 61-62 illustrate a bone biopsy device, often referred to as an I-type bone biopsy device, having a depth stop 253. Typical I-type bone biopsy products require a depth stop 253. They often have adjustment features 252 which include, but are not limited to, threads. However, there are procedures that make use of the full needle length 255 of the device. In this case, the depth stop 253 is removed to expose a longer needle. This may create a problem in that the user is required to disassemble

the product for certain procedures. The illustrated embodiment allows the full needle length 255 of the needle to be initially exposed. The required depth stop 253 may be disposed behind the initial exposed full length 255. This allows the user to perform a procedure that requires the full needle length 255 of the needle without disassembly or assembly processes. There is also no change in technique for other procedures. The depth stop 253 is still available for use with an increased range of adjustable use. This is also advantageous for safety devices. Because there is no assembly or disassembly required, there is less chance that a user will inadvertently activate the safety device while removing the depth stop 253 to access the full needle length 255.

Referring to FIGURES 63-78, there is illustrated additional embodiments of the present invention incorporating a resettable feature. As shown in FIGURES 63-70, an obturator 361 having reset geometry 362 interacts with a reset element 363. The obturator 361 may have a handle 370. The handle 370 may include a cavity 365 to protect the needle 366 during resetting. The obturator 361 may also include a funnel 364 to guide the obturator 361 through the safety shield 369 to the inner diameter of the needle 366. The funnel 364 may include locating surfaces 367 on the housing to facilitate guiding. The funnel 364 is slidable along the obturator 361 such that the funnel 364 allows the obturator 361 to pass through the funnel 364. The funnel 364 may be a separate piece. The obturator 361 may also include a blocking element 368 positioned to prevent resetting. The blocking element 368 may also be movable such that the absence of the blocking element 368 allows the resetting geometry 362 to interact with the reset element 363. The means for moving the blocking element 368 includes, but is not limited to, levers, hinges, buttons, locks, snaps, detents, etc.

In this embodiment the obturator 361 is configured such that after the obturator 361 is through the needle 366 and expels a sample, the blocking element 368 precludes the resetting geometry 362 from interacting with the reset element 363. The blocking member 368 is then moved to a position such that the resetting geometry 362 interacts with the reset element 363. The resetting geometry 362 interacts with the reset element 363 such that the binding member 360 is released from a locked position. This allows the safety shield 369 to be ready for reuse. It is also envisioned that the resetting geometry 362 may be placed in other locations on the obturator 361 including, but not limited to, the opposite end of the obturator 361.

As shown in FIGURES 71-74, a safety shield 389 includes a reset interface 387 that can be manually activated to interact with the reset element 383. The reset interface 387 may be directly connected to the reset element 383. The reset element 383 may also consist as a part of, but not limited to, the following: hub/handle, inner housing, outer housing, binding member, and/or the obturator. Alternatively, the reset element 383 may be a separate piece that interacts with any of the above pieces. The reset interface 387 may be connected to or interact with reset geometry 382 that is intended to interact with the reset element 383 for the purpose of releasing binding member 380 from the locked position. The reset interface 387 may contain, but is not limited to, springs, hinges, levers, buttons, switches, slides, etc. The reset interface 387 may also include a pairing of interfaces. This may be desirable to ensure proper finger placement. The pairing of interfaces may be offset to ensure an intentional effort is given to reset the safety shield.

The reset interface 387 may require an additional aperture plate 388, such that the unlocking of binding from the original locked binding member 380 does not cause the accidental removal of the safety shield 389 from the contaminated sharp. The additional aperture plate 388 can be configured such that the activation of the reset interface 387 positions binding surfaces 386 in the safety shield 389 to facilitate binding when the safety shield 389 is urged distally. This measure can prevent accidental removal of safety shield 389 from a contaminated sharp while allowing resetting to occur.

As illustrated in FIGURES 75-78, a funnel 392 guides an obturator 391 to the inner diameter of a needle 396. The funnel 392 may be configured such that it allows for a locking or friction fit to the needle 396. The funnel 392 may also be configured such that it incorporates locating features 393 on the safety shield 399 for guiding the obturator 391 to the inner diameter of the needle 396. The locating features 393 on the safety shield 399 may also be configured such that a desirable fit is accomplished to maintain position. Such fit interfaces include, but are not limited to, snap fit, friction fit, detents, etc. The option to use the funnel 392 with or with out the safety shield 399 may be desirable so that clinicians may choose to use the funnel 392 with the safety shield 399 protecting the contaminated sharp to guide an obturator 391 to the inner diameter of the needle 396. This also allows for conventional use without safety devices.

Referring to FIGURES 79-92, in certain applications it may be desirable to funnel an obturator through the needle device. It may also be desirable to incorporate this guiding member in a safety shield, which may require activation of the safety shield prior to using the funnel. Furthermore, it may be desirable to reset a binding member that protects a contaminated sharp (e.g. medical needle, stylet, etc.).

One embodiment illustrates a guiding member 402 that is integral to the safety shield 401. The guiding member 402 includes an interface of a particular geometry that allows for guiding a through-the-needle device, such as an obturator 403, etc. The guiding member 402 is configured such that the through-the-needle device 403 cannot interfere with the locking mechanism 404 in the safety shield 401. Other embodiments include a geometry that continues to allow for guiding of guiding member 402, but which also provides reset areas 406 for the safety shield 401.

FIGURES 81-82 show a guiding member 412 having flexible members 415 allowing the guiding member 412 to change sizes. This allows for guiding of a through the needle device 413. The flexible members 415 also allow for a larger opening that provides a reset area 416. The reset area 416 is an area that will allow reset geometry 417, or other geometry that interacts with the reset geometry 417, to be brought into a position such that it interacts with the reset element 418 to allow the binding from the locking mechanism 414 to be released. This allows for the safety shield 411 to be ready for reuse.

As shown in FIGURES 83-85, another embodiment includes a guiding member 422 having adjustable members 425 that can be positioned by a positioning member 429. The adjustable members 425 may be either rigid or flexible. The positioning member 429 may include, but is not limited to, a sleeve, button, lever, collar, or other member intended to interact with the adjustable members 425. The adjustable members 425 are configured such that the positioning member 429 interact with the adjustable members 425 causing the adjustable members 425 to be positioned so as to guide a through-the-needle device 423. The adjustable members 425 may be configured such that a tighter guiding member 422 may be obtained, that otherwise may fit around the needle 420. The positioning member 429 may contain grip surfaces 424. The grip surfaces 424 may be configured such that upon subsequent activation of the safety shield 421, the positioning member 429 will position the flexible members 425 upon activation. The positioning member 429 may also be configured such that the positioning member 429 may be repositioned wherein the adjustable members 425 provide a reset area 426.

As seen in FIGURES 86-88, another embodiment is illustrated wherein a guiding member 432 is integrated with the obturator 431. The guiding member 432 may be configured such that it remains attached to the obturator 431. The guiding member 432 may also be configured such that it is slideable along the obturator 431. This embodiment depicts the guiding member 432 having a spring 433 (see FIGURES 87-88). The spring 433 may include, but is not limited to, a spring, folded plastic, telescoping features, line, wire, etc. It is configured such that the natural resting position of the guiding member 432 is at the end of the obturator 431. This allows for guiding of the obturator 431. The guiding member 432 is configured such that when the needle 430 is brought towards the obturator 431, the guiding member 432 guides the needle to the center. This guiding takes place with little resistance. When the needle 430 contacts the center of the guiding member 432, there are locking surfaces 434 configured such that the needle 430 tends to lock onto the guiding member 432, such as for example a luer taper. After the needle 430 is locked onto the guiding member 432, continued motion tends to make the guiding member 432 slide along the obturator 431. The obturator 431 is then guided into the needle 430 and expels the sample.

As shown in FIGURES 89-90, the obturator handle 445 may be configured such that reset geometry 447 is integrated onto the obturator handle 445. The obturator handle 445 may also contain locking surfaces 444 configured such that the needle 440 tends to lock onto the obturator handle 445.

Other embodiments include modifications to the end sensing member 452 (see FIGURE 91). The end sensing member 452 includes needle communicating surfaces 451 that rides on the needle 450 and provides a force to resist binding. When the geometry of the needle 450 changes (e.g., end of the needle, needle grind, needle taper, etc.), the end sensing member 452 senses the change of the needle 450 and binding is no longer resisted. Changing the needle 450 geometry includes, but is not limited to, angled surfaces, notched surfaces, bumps, or any surface intended to amplify end sensing. Angled surfaces 454 are shown in FIGURE 91. The angled surfaces 454 are configured such that a slight needle 450 geometry change causes the angled surfaces 454 to translate dramatically. This is due to the geometry condition that exists from the angled surfaces 454.

Another embodiment is shown in FIGURE 92 having a separate needle communicating surface 461. This needle communicating surface 461 applies a frictional force to the needle 460. This force is used in combination with needle

communicating members 462 to oppose binding. The frictional force that opposes binding on the needle 460 is available for geometry changes in the needle 460 that prevent the friction forces from being applied (e.g., needle taper, needle grind, end of the needle, etc.).

The invention of the present disclosure may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.